STUDIES ON THE USABLE PROPERTIES OF INNOVATIVE WOUND DRESSINGS

Magdalena Kucharska, Marcin H. Struszczyk[1)], Magdalena Cichecka[1)], Kinga Brzoza

Institute of Biopolymer and Chemical Fibres
ul. M. Sklodowskiej-Curie 19/27, 90-570 Łódź, Poland

[1)]Institute of Security Technologies 'MORATEX'
ul. M. Sklodowskiej-Curie 3, 90-965 Łódź, Poland
e-mail: mstruszczyk@moratex.eu

Abstract
The new implemented wound dressings should meet several requirements connected with the clinical safety and performance. The series of PN-EN 13726 Standards describes the tests methods for the verification the most important parameters related to mentioned performance and safety of a new designed wound dressing being the base for the risk analysis (according to PN-EN ISO 14971:2009 Standard). The aim of the research was to evaluate the behavior of several types of new designed prototypes of innovative wound dressings made of various form of chitosan (such as: foams, films, etc.). The behavior of studied chitosan wound dressings was evaluated before and after of accelerated aging according to ASTM F 1980-07:2002 to establish the effect of the wound dressings storing conditions. The presented study is a continuation of earlier research.

Key words: *wound dressings, microcrystalline chitosan sponges, preclinical studies, medical devices.*

1. Introduction

The stability of behavior of the wound dressings during the storing (life span) is the most important requirement due to necessity of the retain performance and safety guaranteed by the manufacturer. European Directives for medical devices [2, 3] do not contain any harmonized standards describing essential requirements for the estimation of storing period of new-designed medical devices. However, there is one of essential requirement of [2] for providing the documented evidence of the performance and the safety maintained during carrying and storing (in so called post-manufacture phase). For this reason there is need to adopt the validated analytical method for verifying the effect of carrying and storing condition on retain the performance and safety of medical devices.

The main guidance for providing the accelerated aging studies is covering by ASTM F 1980-07:2002 Standard [4]. The main aspect of above-mentioned Standard is rapid determination of the effect of accelerated aging on the sterile integrity of the sterile barrier system and physical behavior of the packaging system materials of medical devices [4]. However, it is easy to implement the guidance of ASTM F 1980-07:2002 Standard for the determination of changes in the performance of medical devices (including wound dressings).

The aim of the study was to evaluate the behavior of new designed prototypes of innovative wound dressings made of various usable form of chitosan after accelerated aging simulated 1 years of storing at real time.

2. Materials and methods

2.1. Materials

The sponges of chitosan or chitosan/alginate fibrides [5, 6] was designed according to the procedure elaborated by IBWCh. Both forms of wound dressings were underwent the sterilization using accelerated electron beams (28 kGy).

The topography of designed wound dressing are shown on ***Figure 1***.

The properties of unsterile and sterile wound dressing before the accelerated aging study is shown in ***Table 1***.

Table 1. *Physical properties of unsterile and sterile sponge wound dressing.*

Wound dressing type	Thickness, mm	Tenacity, MPa	Elongation at break, %
	PN-EN ISO 1923:1999	PN-EN ISO 1798:2009	PN-EN ISO 1798:2009
Unsterile chitosan fibrides sponge	2.82 ± 0.00	0.060 ± 0.005	10.90 ± 1.94
Sterile chitosan fibrides sponge	2.81 ± 0.00	0.057 ± 0.006	4.54 ± 0.98
Unsterile chitosan/alginate fibrides sponge	2.48 ± 0.00	0.056 ± 0.003	14.70 ± 0.60
Sterile chitosan/alginate fibrides sponge	2.84 ±0.00	0.054 ± 0.002	11.10 ± 1.52

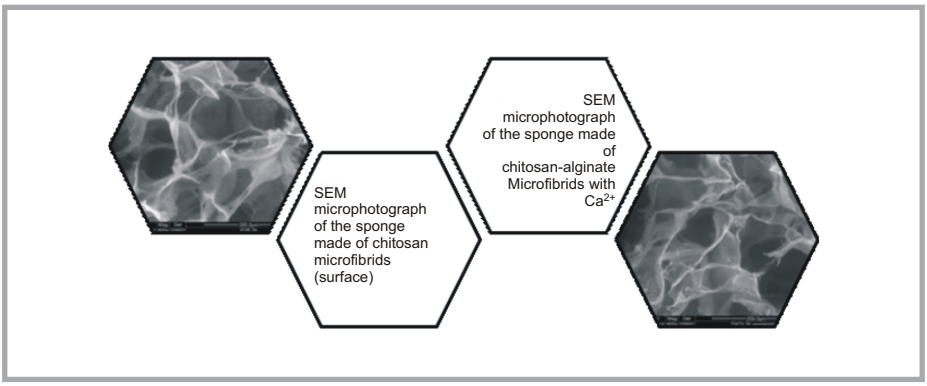

Figure 1. *SEM microphotograph of the designed wound dressings (mag. × 600).*

Table 2. *Range of tested parameters of designed wound dressings before and after accelerated aging study [1].*

Standard	Determined parameters
PN-EN 13726-1:2005 „Test methods for primary wound dressings - Part 1: Aspects of absorbency" [7]	• free swell absorptive capacity; • fluid handling capacity; • gelling properties; • dispersion characteristics.
PN-EN 13726-2:2005 „Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings" [8]	Moisture vapour transmission rate (MVTR) of a wound dressing when in contact with: • water vapour; • liquid.

Table 3. *The applied parameters of the accelerated aging study.*

Aging temperature, °C	Ambient temperature, °C	Formula		Days to age 1 year at ambient temperature	Weeks to age 1 year at ambient temperature
		Days in year	Aging factor		
60	23	365	$2^{3.7}$	28	4

2.2. Methods

Physical and mechanical properties of sponge wound dressings were assessed in the accredited Metrology Laboratory of Institute of Security Technologies „MORATEX" according to PN-EN 13726 Standards in range described in ***Table 2***, before and after accelerated aging test.

The accelerated aging studies was carried out according to ASTM F 1980-07:2002 Standard at temperature of 60 °C for 4 weeks. Taking into the account Aging Temperature Equivalencies (ATE) and Aging Factor (AF) = 2 - 4 weeks of accelerated study is related to 1 year of storing at real time at ambient temperature (23 °C) as shown in ***Table 3***.

Table 4. *Usable properties of sponge wound dressings made of chitosan fibrides before and after accelerated aging.*

Parametr	Sterile sponge wound dressings made of chitosan fibrides	Sterile sponge wound dressings made of chitosan fibrides after 1 year of accelerated aging
Free swell absorptive capacity in g	7.17 ± 0.31	7.74 ± 0.34
Free swell absorptive capacity per 100 cm^2 in g	28.67 ± 1.22	28.16 ± 1.36
Total fluid handling capacity (24h) in g	20.11 ± 1.39	15.34 ± 4.08
Total fluid handling capacity (48h) in g	21.20 ± 0.74	22.22 ± 1.82
MVTR of a wound dressing when in contact with water vapour in $g \cdot m^{-2} \cdot 24^{-1}$	4443 ± 128	5490 ± 230
MVTR of a wound dressing when in contact with water liquid in $g \cdot m^{-2} \cdot 24^{-1}$	13760 ± 1042	8179 ± 141

Table 5. *Usable properties of sponge wound dressings made of chitosan/alginate fibrides before and after accelerated aging.*

Parameter	Sterile sponge wound dressings made of chitosan/alginate fibrides	Sterile sponge wound dressings made of chitosan/alginate fibrides after 1 year of accelerated aging
Free swell absorptive capacity in g	9.18 ± 0.78	6.83 ± 0.29
Free swell absorptive capacity per 100 cm^2 in g	36.72 ± 3.12	27.34 ± 1.16
Total fluid handling capacity (24h) in g	20.76 ± 0.87	18.46 ± 3.79
Total fluid handling capacity (48h) in g	19.76 ± 0.76	20.34 ± 0.28
MVTR of a wound dressing when in contact with water vapour in $g \cdot m^{-2} \cdot 24^{-1}$	6488 ± 216	5338 ± 446
MVTR of a wound dressing when in contact with water liquid in $g \cdot m^{-2} \cdot 24^{-1}$	23778 ± 1667	12284 ± 166

3. Results and discussion

The usable properties of the sponge wound dressings made of chitosan fibrides before and after accelerated aging study simulated 1 year of storing at real time are shown in ***Table 4***.

All determined usable parameters of wound dressings were changed during the accelerated aging test. However, the alteration of the parameters of the sponge wound dressing after accelerated aging allow to remain the appropriate level of the clinical performance and safety [9].

Figure 2 shows the changes in the performance of sponge wound dressings made of chitosan fibrides after accelerated aging in relation to the suitable parameters of initial wound dressings.

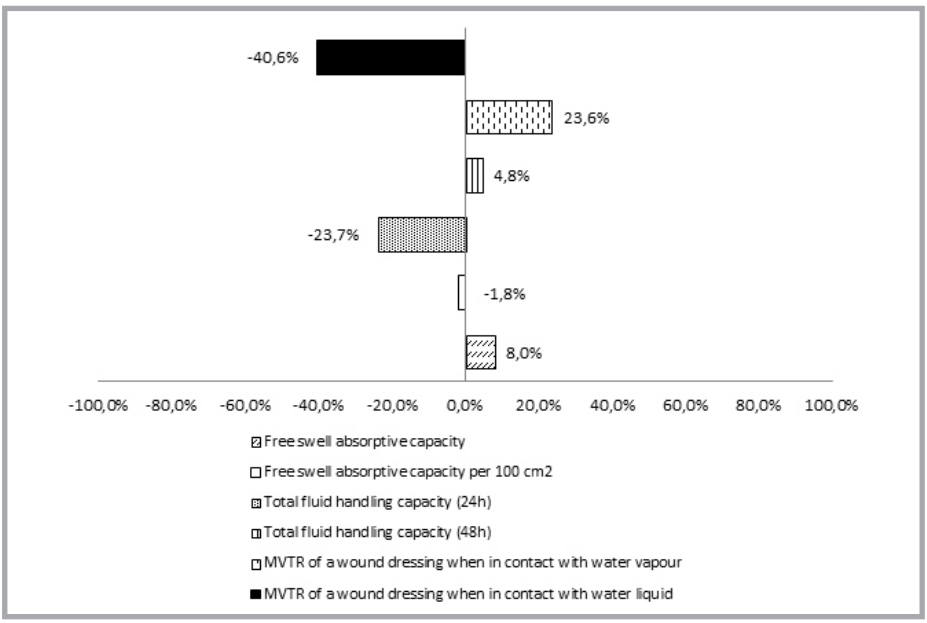

Figure 2. *Changes in the performance (usable parameters) of sponge wound dressings made of chitosan fibrides after accelerated aging in relation to initial parameters (0 level).*

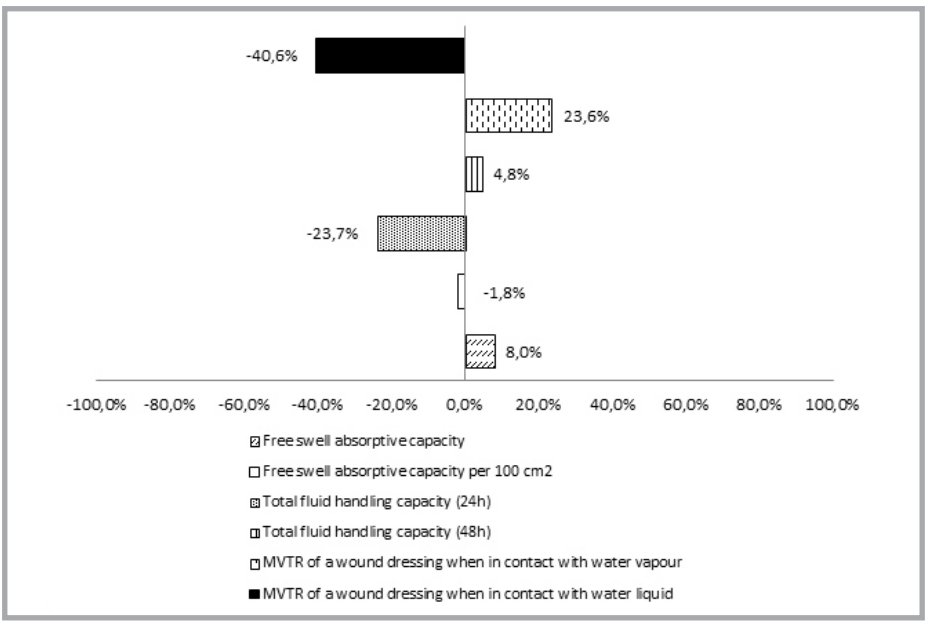

Figure 3. *Changes in the performance (usable parameters) of sponge wound dressings made of chitosan/alginate fibrides after accelerated aging in relation to initial parameters (0 level).*

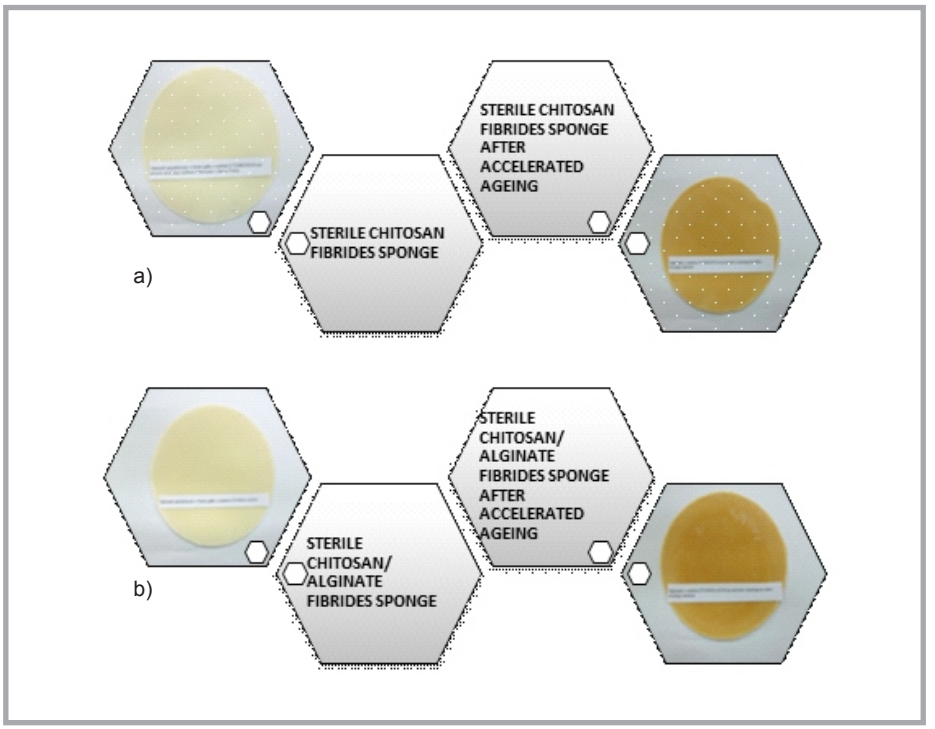

Figure 4. *Change in the view after accelerated aging of the sponge wound dressings made of: a) chitosan fibrides; b) chitosan/alginate fibrides.*

Table 5 shows the results of usable parameters of sponge wound dressings made of chitosan/alginate fibrides before and after accelerated ageing study simulated 1 year at real time storing. The changes in the parameters in respect to the parameters of initial wound dressings are shown on ***Figure 3***.

The accelerated aging negatively affects the all measured usable properties of sponge wound dressings made of chitosan/alginate fibrides. However, the level of alteration did not exceed 50% for accelerated aged sponge wound dressings, both made of chitosan/alginate fibrides as well as of chitosan fibrides (***Figures 2 - 3***).

The effect of accelerated aging on the colour of sponge wound dressings is shown on ***Figure 4***.

The color of sponge wound dressings was drastically changed after accelerated aging, both for sponge wound dressings made of the chitosan or chitosan/alginate fibrides. Above phenomenon is probably connected with the post-radiation sterilization changes in molecular structure of biopolymers deepened by the increase in the temperature during the accelerated aging study. Darkening of the wound dressings is resulted from the cross-linking effects of free-radical originated during the radiation sterilization. The above-thesis will be confirmed in further studies.

4. Conclusions

The behavior of studied chitosan wound dressings was evaluated before and after accelerated ageing according to ASTM F 1980-07:2002 Standard to establish the effect of the wound dressings storing conditions. The tested prototypes of innovative wound dressing did not show significant alteration after the accelerated aging (acc. ASTM F 1980-07:2002 Standard) as compared with the properties of initial wound dressings.

The changes in the color of sponge wound dressings is probably connected with the free-radicals formation after radiation sterilization afterwards resulting in intra- and/or intermolecular cross-linking of biopolymers (chitosan or chitosan and alginate). The more detailed studies are necessary to describe the observed effects.

5. Acknowledgment

The work was carried out within research project No. N N508 389 137 „STUDY ON THE EVALUATION OF THE PROTOTYPES OF INNOVATIVE WOUND DRESSINGS" funded by the Minster of Science and High Education

6. References

1 *Kucharska M., Struszczyk M.H., Cichecka M., Brzoza-Malczewska K., PRELIMINARY STUDIES ON THE USABLE PROPERTIES OF INNOVATIVE WOUND DRESSINGS, Progress in the Chemistry and Application of Chitin and its Derivatives, vol. 16, 2011, 131-137.*

2 *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:pl:PDF [2011-10-20].*

3 *Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:en:PDF [2011-10-20].*

4 *ASTM F 1980-07:2002 Standard Guide for Accelerated Ageing of Sterile Barrier Systems for Medical Devices.*

5 *Kucharska M., Niekraszewicz A., Ciechańska D., Gruchała B., Brzoza-Malczewska K., Wiśniewska-Wrona M., Method of producing fibrids containing chitosan, Patent Applications No. P-385031.*

6 *Kucharska M., Niekraszewicz A., Ciechańska D., Gruchała B., Brzoza-Malczewska K.,. Wiśniewska-Wrona M, Method of producing fibrids containing chitosan, Patent Applications No. P-385032.*

7 *PN-EN 13726-1:2005 „Test methods for primary wound dressings - Part 1: Aspects of absorbency".*

8 *PN-EN 13726-2:2005 „Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings".*

9 *Kucharska M., Struszczyk M.H., Niekraszewicz A., et. al., TROMBOGUARD® - FIRST AID WOUND DRESSING, Progress in the Chemistry and Application of Chitin and its Derivatives, vol. 16, 2011, 121-130.*